

IPW



Docket No: 2685.2001 US2

THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: David A. Edward, Richard P. Batycky, and Lloyd Johnston

Application No.: 10/681,416

Group Art Unit: 1615

Filed: October 8, 2003

Examiner: Not Assigned

Confirmation No.: 7426

Title: Highly Efficient Delivery of a Large Therapeutic Mass Aerosol

CERTIFICATE OF MAILING OR TRANSMISSION

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, or is being facsimile transmitted to the United States Patent and Trademark Office on:

5/10/04 *Hollie Wakefield*

Date Signature

Hollie Wakefield

Typed or printed name of person signing certificate

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

This Information Disclosure Statement is submitted:

under 37 CFR 1.129(a), or  
(First/Second submission after Final Rejection)

under 37 CFR 1.97(b), or  
(Within any one of the following time periods: three months of filing national application (other than a CPA) or date of entry of the national stage in an international application; or before the mailing date of a first office action on the merits in a non-provisional application, including a CPA, or a Request for Continued Examination).

under 37 CFR 1.97(c) together with either:  
 a Statement under 37 CFR 1.97(e), as checked below, or  
 a \$180.00 fee under 37 CFR 1.17(p), or  
(After the 37 CFR 1.97(b) time period, but before final action or notice of allowance, whichever occurs first)

under 37 CFR 1.97(d) together with:  
 a Statement under 37 CFR 1.97(e), as checked below, and  
 a \$180.00 fee under 37 CFR 1.17(p), or  
(Filed after final action or notice of allowance, whichever occurs first, but on or before payment of the issue fee)

under 37 CFR 1.97(i):  
Applicant requests that the IDS and cited reference(s) be placed in the application filewrapper. (Filed after payment of issue fee)

Statement Under 37 CFR 1.97(c)

- Each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement; or
- No item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned, after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of this Information Disclosure Statement.

Statement Under 37 CFR 1.704(d) (Patent Term Adjustment)

(Applies to original applications (other than design) filed on or after May 29, 2000)

- Each item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart application and this communication was not received by any individual designated in -§ 1.56(c) more than thirty days prior to the filing of the Information Disclosure Statement.
- Enclosed herewith is form PTO-1449:
  - Copies of the cited references are enclosed.
- All cited references are those entered in prior applications, U.S. Application Nos. 09/878,146 and 09/591,307, to which priority under 35 U.S.C. 120 is claimed. The earlier application contains copies of the cited references.
- The listed references were cited in the enclosed International Search Report in a counterpart foreign application.
- The “concise explanation” requirement (non-English references) for reference(s) [ ] under 37 CFR 1.98(a)(3) is satisfied by:
  - the explanation provided on the attached sheet.
  - the explanation provided in the Specification.
  - submission of the enclosed International Search Report.
  - submission of the enclosed English-language version of a foreign Search Report and/or foreign Office Action.
  - the enclosed English language abstract.

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The Examiner is requested to return a copy of the list of pending applications indicating which references were considered with the next office communication.

It is requested that the information disclosed herein be made of record in this application.

Method of payment:

- A check for the fee noted above is enclosed, or the fee has been included in the check with the accompanying Reply. A copy of this Statement is enclosed.
- Please charge Deposit Account [ ] in the amount of [ \$ ]. A copy of this Statement is enclosed.
- Please charge any deficiency in fees and credit any overpayment to Deposit Account 502807.

Respectfully submitted,

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N. Chelmsford, MA 01863

Dated: 5/10/04

PTO-1449 REPRODUCED  <b>INFORMATION DISCLOSURE CITATION IN AN APPLICATION</b>  MAY 12 2004  Use several sheets if necessary)		ATTORNEY DOCKET NO. 2685.2001 US2	APPLICATION NO. 10/681,416
APPLICANT David A. Edwards <i>et al.</i>			
FILING DATE October 8, 2003		CONFIRMATION NO. 7426	GROUP 1615

## U.S. PATENT DOCUMENTS

EXAMINER INITIAL	REF. NO.	DOCUMENT NUMBER	ISSUE DATE / PUBLICATION DATE	NAME
	AA	4,069,819	01/24/78	Valentini <i>et al.</i>
	AB	4,995,385	02/26/91	Valentini <i>et al.</i>
	AC	5,260,306	11/09/93	Boardman <i>et al.</i>
	AD	5,304,125	04/19/94	Leith
	AE	5,506,203	04/09/96	Bäckström <i>et al.</i>
	AF	5,518,998	05/21/96	Bäckström <i>et al.</i>
	AG	5,641,510	06/24/97	Clark <i>et al.</i>
	AH	5,642,728	07/01/97	Andersson <i>et al.</i>
	AA2	5,795,594	08/18/98	York <i>et al.</i>
	AB2	5,830,853	11/03/98	Bäckström <i>et al.</i>
	AC2	5,851,453	12/22/98	Hanna <i>et al.</i>
	AD2	5,855,913	01/05/99	Hanes <i>et al.</i>
	AE2	5,874,064	02/23/99	Edwards <i>et al.</i>
	AF2	5,985,309	11/16/99	Edwards <i>et al.</i>
	AG2	5,993,805	11/30/99	Sutton <i>et al.</i>
	AH2	5,997,848	12/07/99	Patton <i>et al.</i>
	AA3	6,019,968	02/01/00	Platz <i>et al.</i>
	AB3	6,051,256	04/18/00	Platz <i>et al.</i>
	AC3	6,063,138	05/16/00	Hanna <i>et al.</i>
	AD3	6,136,295	10/24/00	Edwards <i>et al.</i>
	AE3	6,165,463	12/26/00	Platz <i>et al.</i>
	AF3	6,284,282 B1	09/04/01	Maa <i>et al.</i>
	AG3	6,372,258 B1	04/16/02	Platz <i>et al.</i>

EXAMINER	DATE CONSIDERED
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PTO-1449 REPRODUCED	ATTORNEY DOCKET NO. 2685.2001 US2	APPLICATION NO. 10/681,416
<b>INFORMATION DISCLOSURE CITATION IN AN APPLICATION</b>	<b>APPLICANT</b> David A. Edwards <i>et al.</i>	
May 10, 2004  (Use several sheets if necessary)	FILING DATE October 8, 2003	CONFIRMATION NO. 7426
		GROUP 1615

<b>EXAMINER</b>	<b>DATE CONSIDERED</b>
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## FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	TRANSLATION YES      NO
AL		WO 95/00127	05/01/95	PCT	
AM		WO 96/32096	17/10/96	PCT	
AN		WO 96/32149	17/10/96	PCT	
AO		WO 98/16205	23/04/98	PCT	
AP		WO 98/17257	30/04/98	PCT	
AQ		WO 98/31346	23/07/98	PCT	
AL2		WO 99/16419	08/04/99	PCT	
AM2		WO 99/66903	29/12/99	PCT	
AN2		WO 00/10541	02/03/00	PCT	
AO2		WO 00/33811	15/06/00	PCT	
AP2		WO 01/13893 A2	01/03/01	PCT	
AQ2		WO 01/51030 A1	19/07/01	PCT	
AL3					
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**OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)**

AR	Anderson, S.D. <i>et al.</i> , "A New Method for Bronchial-Provocation Testing in Asthmatic Subjects Using a Dry Powder of Mannitol," <i>Am. J. Respir. Crit. Care Med.</i> 156:758-765 (1997).
AS	Anderson, S.D. <i>et al.</i> , "The Effect of Inhaling a Dry Powder of Sodium Chloride on the Airways of Asthmatic Subjects," <i>Eur. Respir. J.</i> 10:2465-2476 (1997).
AT	Ben-Jebria, A. <i>et al.</i> , "Large Porous Particles for Sustained Protection from Carbachol-Induced Bronchoconstriction in Guinea Pigs," <i>Pharm. Res.</i> 16(4):555-561 (1999).
AU	Cipolla, D. <i>et al.</i> , "Bolus Administration of INS365: Studying the Feasibility of Delivering High Dose Drugs Using the AERx® Pulmonary Delivery System," <i>Respiratory Drug Delivery</i> , VII:231-239 (2000).
AV	Edwards, D.A., "The Macrotransport of Aerosol Particles in the Lung: Aerosol Deposition Phenomena," <i>J. Aerosol Sci.</i> , 26(2):293-317 (1995).
AW	Edwards, D.A. <i>et al.</i> , "Large Porous Particles for Pulmonary Drug Delivery," <i>Science</i> 276:1868-71 (1997).
AX	Huang, C-H. <i>et al.</i> , "Calorimetric and Molecular Mechanics Studies of the Thermotropic Phase Behavior of Membrane Phospholipids," <i>Biochim. Biophys. Acta.</i> , 1422:273-307 (1999).
AY	Pritchard, J.N. <i>et al.</i> , "Use of In Vitro Particle Size Data to Predict Deposition and Effects of Inhaled Drugs," <i>International Conference on Aerosol Therapy</i> . Italy, (1998, December 2-5).
AZ	Scheuch, G. <i>et al.</i> , "Measuring <i>in vivo</i> deposition of large porous particles," <i>Journal of Aerosol Medicine</i> 12(2):127-138 (1999).
AR2	Wang, J. <i>et al.</i> , "Inhalation of Estradiol for Sustained Systemic Delivery," <i>Journal of Aerosol Medicine</i> , 12(1):27-36 (1999).
AS2	Wolff, R.K., "Safety of Inhaled Proteins for Therapeutic Use," <i>Journal of Aerosol Medicine</i> , 11(4):197-219 (1998).
AT2	
AU2	
AV2	
AW2	
AX2	

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